



Record of Decision

DEC 25-H113

In the Matter of

Licensee

McMaster University

Purpose

Temporary exemption under section 7 of the *Nuclear Safety and Control Act* to increase the total activity limits of Nuclear Substances and Radiation Devices
Licence No. 01495-19-26.3

Record of
Decision Date

September 29, 2025

RECORD OF DECISION – DEC 25-H113

Licensee: McMaster University

Address/Location: 1280 Main Street West, Hamilton, Ontario, L8S 4K1

Purpose: Temporary exemption under section 7 of the Nuclear Safety and Control Act to increase the total activity limits of Nuclear Substances and Radiation Devices
Licence No. 01495-19-26.3

Date of Application: May 21, 2025

Date of Decision: September 29, 2025

Panel of Commission: P. Tremblay, President

Exemption from the *Class I Nuclear Facilities Regulations*:
Granted until September 30, 2027

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1.0 INTRODUCTION

1. McMaster University has applied to the Canadian Nuclear Safety Commission¹ (CNSC) for a temporary exemption from the [*Class I Nuclear Facilities Regulations*](#)² (CINFR) for its nuclear substances and radiation devices (NSRD) licence no. 01495-19-26.3.³ McMaster's NSRD licence authorizes it to repackage lutetium-177 (Lu-177) at its Centre for Advanced Nuclear Systems (CANS) facility and is valid until December 31, 2026.
2. McMaster University is located at 1280 Main Street West in Hamilton, Ontario. This is on the traditional territory of the Haudenosaunee and Anishinabe peoples. This territory is covered by the Between the Lakes Purchase and the "Dish With One Spoon" wampum agreement.
3. Under its current NSRD licence, McMaster can use up to 1000 terabecquerels⁴ (TBq) of nuclear substances at its CANS facility. To use over 1000 TBq of nuclear substances would subject the CANS facility to the CINFR, as a Class IB facility.⁵
4. To facilitate an increased demand for its services, McMaster intends to apply for a Class IB licence for its CANS facility. Such an application would be subject to a separate public hearing. In the meantime, McMaster has requested a temporary exemption from the CINFR to allow it to repackage Lu-177 at quantities above those set out for NSRD licensees.

2.0 DECISION

5. For the reasons described below, the Commission temporarily exempts McMaster from the application of the CINFR. Under this exemption, the Commission authorizes the following annual activity limits:
 - 8500 TBq of Lu-177
 - 2100 TBq of ytterbium-175⁶ (Yb-175)
 - 2200 TBq of activated materials

This temporary exemption is valid until September 30, 2027, and is subject to McMaster continuing to hold a valid NSRD licence.

¹ The *Canadian Nuclear Safety Commission* is referred to as the "CNSC" when referring to the organization and its staff in general, and as the "Commission" when referring to the tribunal component.

² SOR/2000-204.

³ McMaster's application states that the current licence is no. 01495-19-26.2. Since the submission of McMaster's application, the licence was amended in June 2025. Therefore, the current licence number is 01495-19-26.3.

⁴ The becquerel is the SI unit of radioactivity. One becquerel is the activity of a quantity of radioactive material in which one nucleus decays per second. One terabecquerel is equal to one trillion becquerels.

⁵ The CINFR define a Class IB facility, in part, as a plant, other than a Class II nuclear facility as defined in section 1 of the [*Class II Nuclear Facilities and Prescribed Equipment Regulations*](#), for the processing or use, in a quantity greater than 10¹⁵ becquerels per calendar year, of nuclear substances other than uranium, thorium or plutonium.

⁶ Yb-175 is an impurity generated from ytterbium-174 (Yb-174) during target irradiation.

6. The Commission understands that, following the issuance of this decision, a CNSC Designated Officer can amend NSRD licence 01495-19-26.3 to include the annual activity limits stated in paragraph 5 of this *Record of Decision*.
7. To ensure enhanced regulatory oversight during the temporary exemption period, the Commission expects McMaster to submit a quarterly report on its Lu-177 repackaging activities to CNSC staff. This quarterly report should include worker doses and environmental releases to ensure that the environment and the health and safety of persons continues to be protected during the exemption period. The Commission understands that a CNSC Designated Officer intends to include this quarterly report as a requirement in the amended NSRD licence.

3.0 ISSUES

8. The Commission may, in accordance with the [*General Nuclear Safety and Control Regulations*](#)⁷ (GNSCR), exempt any activity, person, class of person or quantity of a nuclear substance, temporarily or permanently, from the application of the NSCA or the regulations made under it.⁸ Subsection 11 of the GNSCR states that the Commission may grant an exemption if doing so will not:
 - (a) pose an unreasonable risk to the environment or the health and safety of persons;
 - (b) pose an unreasonable risk to national security; or
 - (c) result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.

4.0 COMMISSION PROCEDURES

9. Pursuant to section 22 of the NSCA, the President of the Commission established himself as a Panel of the Commission to consider McMaster's application. The Commission, in conducting a public hearing based on written materials, considered written submissions from McMaster ([Application](#)) and CNSC staff ([CMD 25-H113](#)).
10. In making its decision, the Commission sent questions to CNSC staff through [CMD 25-H113-Q](#). CNSC staff provided responses to the Commission's questions in [CMD 25-H113.A](#). The Commission is satisfied with the responses provided by CNSC staff.

5.0 COMMISSION FINDINGS

11. In considering the requested exemption, the Commission considered the applicability of the conditions set out in subsection 11 of the GNSCR.

⁷ SOR/2000-202.

⁸ Section 7 of the NSCA.

5.1 The exemption will not pose an unreasonable risk to the environment or the health and safety of persons

12. For the reasons described below, the Commission is satisfied that the temporary exemption will not pose an unreasonable risk to the environment or the health and safety of persons.
13. Lu-177 is a medical radioisotope used for cancer treatments. CNSC licensees in Canada currently produce Lu-177, repackage it, and then ship it to Germany to be processed into a therapeutic radiopharmaceutical. Repackaging lowers the total activity of the Lu-177 package to the point where it can be shipped to Germany by air.
14. The Lu-177 repackaging process, also referred to as decanning, involves the following steps:
 - receipt of the irradiated targets
 - removal of the sealed Lu-177 ampoules from their aluminum target holders
 - repackaging of the sealed ampoules into CNSC certified Type B transport packages
15. McMaster conducts repackaging activities within a hot cell at the CANS facility. Lu-177 ampoules remain sealed during repackaging and are not subject to any processing at the CANS facility. Due to the relatively short half-life of Lu-177 (6.6 days), McMaster immediately ships the ampoules following repackaging and does not maintain an inventory of Lu-177 on-site.
16. As part of its exemption request, McMaster requested that the Commission temporarily authorize the following annual activity limits under McMaster's current NSRD licence:⁹
 - 8500 TBq of Lu-177
 - 2100 TBq of Yb-175
 - 2200 TBq of activated materials

Health and Safety of Workers

17. McMaster reported that all workers qualified to conduct Lu-177 repackaging activities at the CANS facility are designated as nuclear energy workers (NEWs). To track worker dose, each worker is issued a thermoluminescent whole body dosimeter (TLD), an extremity dosimeter, and an electronic personal dosimeter.¹⁰
18. McMaster submitted data on the doses received by workers since McMaster began repackaging Lu-177 in 2023. From August 2023 to April 2025, no worker received a dose over 1 millisievert per year (mSv/y). This is well below McMaster's administrative control level (15 mSv/y) and the regulatory dose limit for NEWs (50 mSv/y or 100 mSv in a 5-year dosimetry period).¹¹

⁹ Section 1.1, McMaster's application.

¹⁰ Section 2.3, McMaster's application.

¹¹ Section 2.3, McMaster's application.

19. Each ampoule contains approximately the same activity of Lu-177 and Yb-175 and, consequently, the number of ampoules handled is directly proportional to the dose received by each worker. McMaster conducted a conservative dose projection¹² to account for the additional ampoules that would be repackaged under the proposed temporary exemption. McMaster found that occupational doses would remain below both administrative control levels and regulatory dose limits, should the exemption be granted.¹³
20. CNSC staff submitted that McMaster has a process in place to safely manage Lu-177 repackaging. CNSC staff last inspected McMaster's process in May 2025. The only non-compliance found during that inspection was a low-risk finding related to record-keeping. CNSC staff assessed that McMaster's existing process is sufficient to manage the increased repackaging activities without significantly increasing worker dose.¹⁴
21. In CMD 25-H113-Q, the Commission asked CNSC staff to explain how the proposed exemption would not pose an unreasonable risk to the environment or the health and safety of persons. In CMD 25-H113.A, CNSC staff explained that the requested exemption would not increase risk because it would not impact McMaster's current Lu-177 repackaging process, would not result in an accumulation of Lu-177 inventory on-site, and is not expected to significantly increase radiation doses to workers or environmental releases.
22. In CMD 25-H113-Q, the Commission also asked CNSC staff to detail any additional regulatory oversight measures that it would implement during the temporary exemption. CNSC staff submitted that it would add Lu-177 repackaging to the agenda for its regular meetings with McMaster, require McMaster to provide a quarterly report to CNSC staff on worker dose and environmental releases associated with Lu-177 repackaging activities, and conduct a follow-up inspection of McMaster's NSRD licence in the 2026/2027 fiscal year.¹⁵
23. CNSC staff noted that, should the Commission grant the proposed exemption, a CNSC Designated Officer would amend the NSRD licence to reflect the new annual activity limits, to include the commitment to provide a quarterly report to the CNSC, and to update the expiry date to September 30, 2027.¹⁶
24. The Commission is satisfied that the temporary exemption would not pose an unreasonable risk to the health and safety of workers. The Commission bases its conclusion on the following:
 - McMaster has a satisfactory process in place to place to manage worker dose while conducting repackaging activities
 - McMaster provides its workers with adequate dosimetry
 - the Commission is satisfied that occupational doses would remain well below

¹² The projection was considered to be conservative because it assumed that the same worker would be conducting the work each week for the entire year.

¹³ Section 2.4, McMaster's application.

¹⁴ Response to Question 1, CMD 25-H113.A.

¹⁵ Response to Question 1, CMD 25-H113.A.

¹⁶ Response to Question 2, CMD 25-H113.A.

both administrative control levels and regulatory dose limits, should the temporary exemption be authorized

- McMaster committed to submitting a quarterly report to the CNSC during the temporary exemption period that will include worker dose data

Health and Safety of the Public and the Environment

25. McMaster reported that it conducts routine environmental monitoring at the CANS facility including:

- using environmental TLDs to monitor radiation fields in both work areas and publicly accessible areas
- using continuous air monitors to monitor alpha and beta-emitting particles both within the facility, and within the facility's exhaust

McMaster also established conservative airborne contamination monitoring trigger levels to ensure that any unanticipated airborne releases are identified early.¹⁷

26. McMaster reported that, based on its environmental monitoring results since 2023, Lu-177 repackaging activities have had negligible impact on the environment and the health and safety of the public. Between 2023 and 2024,¹⁸ the highest dose recorded by an environmental TLD at the CANS facility was 0.1 mSv. Since 2023, no airborne contamination trigger levels have been exceeded.¹⁹
27. CNSC staff reviewed McMaster's environmental TLD and air monitoring data and found that environmental releases from the CANS facility have remained protective of the public and the environment. CNSC staff noted that, based on the annual activity limits proposed by McMaster, the increase in Lu-177 repackaging activities would not significantly increase doses to the public.²⁰
28. CNSC staff reported that, in April 2025, an event occurred at the CANS facility where a Lu-177 ampoule was broken within the hot cell. This event did not result in any increase to worker dose or releases to the environment. CNSC staff noted that McMaster has a well-developed emergency response program in place which was used to effectively manage the event. CNSC staff added that the program is adequate to manage any future events that may occur under the proposed exemption.²¹
29. The Commission is satisfied that the temporary exemption would not pose an unreasonable risk to the health and safety of the environment or the public. The Commission bases its conclusion on the following:
- environmental monitoring data has shown that Lu-177 repackaging activities have had negligible impact on the environment and the health and safety of the public

¹⁷ Section 2.5, McMaster's application.

¹⁸ 2025 data was not available at the time of McMaster's application.

¹⁹ Section 2.5, McMaster's application.

²⁰ Section 3.5, CMD 25-H113 and Response to Question 1, CMD 25-H113.A.

²¹ Section 3.6, CMD 25-H113.

- the increase in Lu-177 repackaging activities that would be authorized under the requested exemption would not significantly increase doses to the public
- McMaster has an adequate emergency response program in place to manage emergencies while protecting the health and safety of workers, the public, and the environment
- McMaster committed to submitting a quarterly report to the CNSC during the temporary exemption period that will include releases to the environment

5.2 The exemption will not pose an unreasonable risk to national security or result in a failure to satisfy Canada's international obligations

30. For the reasons described below, the Commission is satisfied that the temporary exemption will not pose an unreasonable risk to national security or result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.
31. As discussed in section 5.1 of this *Record of Decision*, the proposed exemption is not anticipated to increase the risk associated with the repackaging of Lu-177 at the CANS facility. McMaster has a process in place to safely manage Lu-177 repackaging and has successfully followed this program since 2023. The requested exemption would not impact McMaster's current Lu-177 repackaging process, would not result in an accumulation of Lu-177 inventory on-site, and is not expected to significantly increase worker dose or environmental releases.
32. Under the NSCA and its regulations, licensees are required to have measures to control access to, and prevent loss, of nuclear substances. Regarding the secure management of Lu-177, McMaster reported that:²²
 - McMaster has a comprehensive procedure to manage the receipt of shipments, which includes verifying shipment contents against documentation and conducting contamination monitoring upon receipt
 - access to areas where repackaging activities take place is restricted to authorized personnel via key card entry
 - after the Lu-177 ampoules are repackaged into CNSC certified Type B transport packages, they are transferred to a secure storage location within the CANS facility
 - the transport packages are surveyed and labelled in accordance with the [*Packaging and Transportation of Nuclear Substances Regulations*](#)²³
 - a qualified carrier transfers the transport packages to the airport within 14-16 hours of the Lu-117 ampoules arriving at the CANS facility
33. Canada's international obligations refer to the obligations arising from the Canada/ International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the [*Treaty on the Non-Proliferation of Nuclear Weapons*](#)

²² Section 1.1, McMaster's application.

²³ SOR/2015-145.

(NPT).²⁴ Pursuant to the NPT, Canada has entered into a [*Comprehensive Safeguards Agreement*](#)²⁵ and an [*Additional Protocol*](#)²⁶ (safeguards agreements) with the IAEA. The objective of these safeguards agreements is for the IAEA to provide credible assurance on an annual basis to Canada and to the international community that all declared nuclear material is in peaceful, non-explosive uses and that there is no undeclared nuclear material or activity in this country

34. McMaster's current NSRD licence requires McMaster to implement and maintain a safeguards program in accordance with the requirements set out in [*REGDOC-2.13.1, Safeguards and Nuclear Material Accountancy*](#).²⁷
35. The Commission notes that, as defined in REGDOC-2.13.1, Lu-177 is not nuclear material subject to safeguards requirements under the safeguards agreements.²⁸
36. The Commission is satisfied that the temporary exemption would not pose an unreasonable risk to nuclear security and will not impact Canada's ability achieve conformity with measures of control and international obligations to which Canada has agreed. The Commission bases its conclusion on the following:
 - the proposed exemption is not anticipated to increase the risk associated with the repackaging of Lu-177 at the CANS facility
 - McMaster has a process in place to control access to, and prevent loss of, nuclear substances
 - the repackaging of Lu-177 does not involve nuclear material to which safeguards agreements apply

5.3 The temporary exemption will expire on September 30, 2027

37. McMaster requested that the Commission authorize this temporary exemption until December 31, 2029, asserting that this should provide enough time for its Class IB licence application to be processed.²⁹
38. In CMD 25-H113, CNSC staff initially recommended that the Commission authorize the temporary exemption until the expiry date of McMaster's current NSRD licence on December 31, 2026. In CMD 25-H113.A, CNSC staff revised its recommendation to September 30, 2027, in an effort to reduce regulatory burden on McMaster by reducing the likelihood that an additional exemption application will be required.
39. The Commission is satisfied that an exemption expiry date of September 30, 2027, is appropriate. The Commission finds that this expiry date reduces regulatory burden on the licensee while ensuring that the temporary exemption does not pose unreasonable risk.

²⁴ INFCIRC/140.

²⁵ INFCIRC/164.

²⁶ INFCIRC/164/Add.1.


²⁷ CNSC Regulatory Document REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*, CNSC, February 2018.

²⁸ CNSC Regulatory Document REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*, CNSC, February 2018.

²⁹ Section 1.1, McMaster's application.

6.0 CONCLUSION

40. Based on the information on the record, the Commission finds that the temporary exemption will not:
- (a) pose an unreasonable risk to the environment or the health and safety of persons;
 - (b) pose an unreasonable risk to national security; or
 - (c) result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.
41. Therefore, pursuant to section 7 of the NSCA, the Commission temporarily exempts McMaster from the application of the CINFR until September 30, 2027, subject to McMaster continuing to hold a valid NSRD licence. Under this exemption, the Commission authorizes the following annual activity limits:
- 8500 TBq of Lu-177
 - 2100 TBq of Yb-175
 - 2200 TBq of activated materials
42. The Commission understands that, following the issuance of this decision, a CNSC Designated Officer can amend NSRD licence 01495-19-26.3 to:
- include the annual activity limits subject to the exemption
 - include a commitment to provide a quarterly report on Lu-177 repackaging activities to the CNSC, as described in paragraph 7 of this *Record of Decision*


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Pierre F. Tremblay
President
Canadian Nuclear Safety Commission

September 29, 2025
Date